

REMARKS

Claims 1-60 are pending. Claims 1-22, 24, 26, and 29-37 stand withdrawn. Claims 28, 38, 41-56, and 58-60, have been amended to correct typographical errors and to more clearly delineate the invention. Support for the amendments and new claims can be found throughout the specification and claims as originally filed. No new matter has been added.

Rejection under 35 U.S.C. 102

Claims 23, 25, 27, 28, 40, 42-45, 48, 49, 54, and 57 are rejected under 35 U.S.C. 102(b) as anticipated by Suverkrup (US 6,228,381). It is alleged that Suverkrup discloses a lyophilized composition comprising a xerogel carrier and an active compound. Applicants disagree and respectfully traverse.

Suverkrup is directed towards "the combination of three elements, namely the application of a drop of the solution of a hydrophilic polymer, which can contain pharmacologically active substances, to a hydrophobic carrier, and the preparation of an anhydrous lyophilizate in situ. Only when these three subaspects are fulfilled at the same time are the aims and advantages according to the invention realized." (Suverkrup column 2, lines 60-67). Thus, Suverkrup teaches that the active compound is dissolved in a polymer which is then added to a carrier. Further confirmation that Suverkrup requires an active compound be dissolved in a polymer prior to addition to a carrier, is found at least at column 3, lines 2-5, which provides a "hydrophilic polymer in which one or more pharmacologically active substances can be dissolved being present in the form of a highly porous lyophilizate." The Suverkrup teaching thus inherently results in distribution of the active agent in the hydrogel to that achieved by dissolution of the active agent in the polymer, the random distribution resulting from application of that active agent/polymer solution to the hydrophobic carrier, and further subsequent random distribution attributable to formation of the lyophilized form.

In contrast to Suverkrup, the Applicants' claimed composition/delivery system does not require that the active ingredient be dissolved in a polymer prior to application to the carrier. The examples of the application as filed (WO 2005/084650), found at pages 20-27, clearly show that the active ingredient to be applied to a xerogel, not dissolved in a polymer. Thus Suverkrup does not teach each and every element of Applicants' claimed subject matter, and as such does not render Applicants' claims non-novel.

The Applicants' examples show that the active ingredient is typically dissolved in water, along with minute amounts of an excipient or surfactant. Additional support that the Applicants' invention includes an active ingredient that is not dissolved in a polymer, can be found at least at page 11, lines 3-6, and page 14, line 30 through page 15, line 3 (WO 2005/084650). The active ingredient aqueous solution is then applied to the xerogel as microdroplets. Thus Applicants' claimed subject matter is a xerogel having had the active agent applied to it; and further, that application results in a locally defined distribution of active agent in the xerogel (that is, controlled distribution via the "printing" process, as is delineated in Applicants' specification). Clearly, the Applicants' invention does not contemplate dissolving the active ingredient into a polymer prior to application to a carrier, and Applicants' claimed subject matter is distinct and distinguishable from the material described by Suverkrup wherein: (i) the dissolution of the active agent in the polymer; (ii) the random distribution resulting from application of that active agent/polymer solution to the hydrophobic carrier; and (iii) further subsequent random distribution attributable to formation of the lyophilized form; combine in a random manner to result in the random distribution of the active agent in the Suverkrup xerogel formed by formation of the xerogel with the active agent solution in it (as opposed to Applicants' formed xerogel that then has the active agent applied to it). As such, Suverkrup fails to disclose each and every element of Applicants' claimed subject matter; that is, Suverkrup at least fails to teach Applicants' xerogel having controlled, "locally defined", distribution of the active agent in the xerogel.

Based on the arguments presented above and the claims as amended, the rejection is overcome. Withdrawal of the rejection is respectfully requested.

Rejection under 35 U.S.C. 103

Claims 38, 39, 41, 46, 47, 50-53, and 58-60 are rejected under 35 U.S.C. 103(a) as unpatentable over Suverkrup (US 6,228,381) in view of Becher (DE 19940241). It is alleged that Suverkrup discloses a lyophilized composition comprising a xerogel carrier and an active compound but does not disclose that the composition is applied only to the surface on a particularly shaped carrier. It is then alleged that Becher provides for such a deficiency. Applicants disagree and respectfully traverse in view of the amendments made herein.

As discussed above, Suverkrup does not provide for the Applicants' claimed invention. Applicants further submit that Becher does not correct the deficiencies of Suverkrup to arrive at the Applicants' claimed invention. Specifically, Becher does not provide any indication of a delivery system comprising a carrier and an active ingredient that is vacuum-dried or freeze-dried, wherein the active ingredient is not dissolved in a polymer. Specifically, the English language translation of the abstract of Becher reads "Applying at least one active substance to one or both sides of a thin substrate forming a carrier layer comprising production of active substances in liquid state so that they are applicable by bubble jet printing techniques, is new."

To properly determine a *prima facie* case of obviousness, the Examiner "must step backward in time and into the shoes worn by the hypothetical 'person of ordinary skill in the art' when the invention was unknown and just before it was made." M.P.E.P. § 2142. This is important as "impermissible hindsight must be avoided and the legal conclusion must be gleaned from the prior art." *Id.* Three criteria may be helpful in determining whether claimed subject matter is obvious under 103(a): first, if there is some suggestion or motivation to modify or combine the cited references; second, if there is a reasonable expectation of success; and third, if the prior art references teach

or suggest all the claim limitations. *KSR Int'l Co. v. Teleflex, Inc.* No 04-1350 (U.S. Apr. 30, 2007). Additional standards regarding a *prima facie* case of obviousness include the following: the mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination. *In re Mills*, 916 F.3d 690 (Fed. Cir. 1990). "Knowledge in the prior art of every element of a patent claim ... is not of itself sufficient to render claim obvious." *Graham v. John Deere Co.*, 383 U.S. 1, 17-18 (1966); *Teleflex, Inc. v. Ficoso N. Am. Corp.*, 299 F.3d 1313, 1333-34 (Fed. Cir. 2002)]. The issue is whether there is an apparent reason to combine the known elements in the fashion claimed by the patent at issue. *KSR Int'l Co. v. Teleflex, Inc.*

Based on the above, Applicants submit that the combination of Suverkrup and Becher fails to arrive at the Applicants' claimed invention. Specifically, Becher fails to rectify the previously discussed deficiencies of Suverkrup. Moreover, Becher does not provide any indication wherein the active ingredient is applied in a locally defined distribution manner. Based on the arguments presented above and the claims as amended, the rejection is overcome. Withdrawal of the rejection is respectfully requested.

Claims 55 and 56 are rejected under 35 U.S.C. 103(a) as unpatentable over Suverkrup (US 6,228,381) in view of Wang (US 5,166,058). It is alleged that Suverkrup discloses a lyophilized composition comprising a xerogel carrier and an active compound but does not disclose that the composition is applied only to the surface on a particularly shaped carrier. It is then alleged that Wang teaches the use of proteins as a wound healing active agent. Applicants disagree and respectfully traverse in view of the amendments made herein.

As discussed above, Suverkrup does not provide for the Applicants' claimed invention. Applicants further submit that Wang does not correct the deficiencies of Suverkrup to arrive at the Applicants' claimed invention. Specifically, Wang does not

provide any indication of a delivery system, does not provide any indication of a carrier, does not provide any indication of an active ingredient that is vacuum-dried or freeze-dried, and does not provide any indication wherein the active ingredient is applied in a locally defined distribution manner to be added to a carrier.

To properly determine a *prima facie* case of obviousness, the Examiner "must step backward in time and into the shoes worn by the hypothetical 'person of ordinary skill in the art' when the invention was unknown and just before it was made." M.P.E.P § 2142. This is important as "impermissible hindsight must be avoided and the legal conclusion must be gleaned from the prior art." *Id.* Three criteria may be helpful in determining whether claimed subject matter is obvious under 103(a): first, if there is some suggestion or motivation to modify or combine the cited references; second, if there is a reasonable expectation of success; and third, if the prior art references teach or suggest all the claim limitations. *KSR Int'l Co. v. Teleflex, Inc.* No 04-1350 (U.S. Apr. 30, 2007). Additional standards regarding a *prima facie* case of obviousness include the following: the mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination. *In re Mills*, 916 F.3d 690 (Fed. Cir. 1990). "Knowledge in the prior art of every element of a patent claim ... is not of itself sufficient to render claim obvious." *Graham v. John Deere Co.*, 383 U.S. 1, 17-18 (1966); *Teleflex, Inc. v. Ficoso N. Am. Corp.*, 299 F.3d 1313, 1333-34 (Fed. Cir. 2002)]. The issue is whether there is an apparent reason to combine the known elements in the fashion claimed by the patent at issue. *KSR Int'l Co. v. Teleflex, Inc.*

Based on the above, Applicants submit that the combination of Suverkrup and Wang fails to arrive at the Applicants' claimed invention. Specifically, Wang fails to rectify the previously discussed deficiencies of Suverkrup. Based on the arguments presented above and the claims as amended, the rejection is overcome. Withdrawal of the rejection is respectfully requested.

Double Patenting Rejections

Claims 23, 25, 27, 28, 40, 42-45, 48, 49, 54-56, and 57 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as unpatentable over claims 22-25, 27-36, 39, and 43-45 of USSN 11/661,726, in view of Suverkrup.

Claims 38, 39, 41, 46, 47, 50-53, and 58-60 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as unpatentable over claims 22-25, 27-36, 39, and 43-45 of USSN 11/661,726, in view of Suverkrup and further in view of Becher.

USSN 11/661,726 has not matured into a US patent. However, Applicants are amenable to addressing the rejection upon notification of allowable subject matter.

The Director is hereby authorized to charge any credits or deficiency in the fees filed (or with any paper hereafter filed in this application by this firm) to our Deposit Account No. 04-1105, under Order No. 66188 (310089).

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Respectfully submitted,

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